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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,609	01/23/2006	Hubert Dumont	MC089P	6220
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MERCK			MERCIER, MELISSA S	
P O BOX 2000			ART UNIT	PAPER NUMBER
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05/13/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/565,609	<b>Applicant(s)</b> DUMONT ET AL.
	<b>Examiner</b> MELISSA S. MERCIER	<b>Art Unit</b> 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

1) Responsive to communication(s) filed on **2-17-10**.  
 2a) This action is **FINAL**.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

4) Claim(s) **4-16** is/are pending in the application.  
 4a) Of the above claim(s) **7-16** is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) **4-6** is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Summary***

Receipt of Applicants Remarks and Amended Claims filed on February 17, 2010 is acknowledged. Claims 4-16 remain pending in this application.

### ***Response to Amendment***

Newly amended claims 7-16 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Applicant has amended claims 7-16 to recite a process of making the originally claimed composition. The original claim language was drawn to product by process claims and not process claims. Applicant was directed to MPEP 2113.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 7-16 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Maintained Rejections***

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehta (US Patent 5,084,278).

The claims are drawn to a pharmaceutical composition comprising cores coated with a taste masking solution.

Mehta discloses taste masked pharmaceutical compositions. The compositions comprise;

a. a pharmaceutical core which is further comprised of a pharmaceutically active dose of a compound, and

b. a microencapsulating polymer which coats the pharmaceutical core and is capable of taste masking the active compound.

The polymeric coating can further comprise diluents, fillers, bulking agents, plasticizers, pigments and opacifiers (abstract).

The cores are in the form of microcapsules (column 2, lines 20-37). The coated microcapsules are used to prepare chewable tablets or capsules (column 2, lines 52-56).

The polymeric coating is preferably a mixture of at least about 5% of a high temperature film forming polymer and about 5% of a low temperature film forming polymer based on the total weight of the polymer in the microcapsule coating. Examples of high temperature polymers include HPMC and numerous Eudragit copolymers (column 4, lines 24-62).

Diluents, including mannitol, in the amount of 0.1-95% by weight of the core material can be included (column 8, lines 3-24). The coating can also comprise a sweetener, such as aspartame in a preferable amount of 0.5% by weight of the total weight of the capsule (column 9, lines 64-68). Flavoring agents including cherry in an amount of at most 2% can also be included (column 10, lines 1-8).

The pharmaceutical core is coated with the taste masking polymer utilizing fluid bed equipment (column 9, lines 1-4).

Mehta does not disclose the use of etoricoxib. However, Mehta discloses the use of taste masking coating is particularly useful in bitter or unpleasant tasting drugs or active agents. Etoricoxib known to be extremely bitter.

It would have been obvious to one of ordinary skill in the art to have used the coating compositions as disclosed by Mehta in order to mask the bitter or unpleasant taste of etoricoxib in order to prepare a compositions which mask the taste of the drug and lead to a higher patient compliance which had been lost due to the unpleasant taste.

***Response to Arguments***

Applicant's arguments have been fully considered but they are not persuasive. Applicant argues:

**\*Mehta does not disclose the combination of components recited in claim**

**4.**

The Examiner respectfully disagrees. Mehta discloses cores comprising a polymeric coating which contains all the recited components. It is unclear to the Examiner what limitations Applicant alleges are not disclosed. Clarification is requested.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is (571)272-9039. The examiner can normally be reached on 8:00am-4:30pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/  
Examiner, Art Unit 1615

/Carlos A. Azpuru/  
Primary Examiner, Art Unit 1615

Application/Control Number: 10/565,609  
Art Unit: 1615

Page 7